DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/27/09 has been entered.

Receipt is acknowledged of the Amendments and Remarks filed on 07/27/09. Claims 1 and 24 have been amended and no claims have been cancelled or added. Accordingly, claims **1-2 and 4-25** remain pending.

NOTE: The Amendments and the Response of 07/27/09 list a wrong Serial number on top of these pages. The correct serial number for this case is 10501485 (not 10530984).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering particles comprising certain active

agents such as bronchodilators and steroids, including salmeterol, fluticasone, formoterol or budesonide, does not reasonably provide enablement for a method of treating ANY respiratory disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "*undue*". See ***In re Wands, 858 F.2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1998).*** The court set forth the eight factors to consider when assessing if a disclosure would require undue experimentation. Citing *Ex parte Forman, 230 USPQ 546*, the court recited eight factors

These factors include, but are not limited to:

1) The breadth of the claims,

2) The nature of the invention,

3) The state of the prior art,

4) The level of one of ordinary skill,

5) The level of predictability in the art,

6) The amount of direction provided by the inventor,

7) The existence of working examples

8) The quantity of experimentation needed to male or use the invention based on the content of the disclosure.

(1 and 2) *The breadth of the claims and the nature of the invention:* The claims are broad. The claims are drawn to a method of treating a respiratory disease by administering (e.g. by inhalation) a medicine of a hollow microporous particles to a patient wherein the particles comprise an active agent.

(3 and 5) *The state of the prior art and the level of predictability in the art:* The art teaches methods of treating disorders such as COPD and asthma by inhalation of active agents such as tiotropium bromide. It is known in the art that tiotropium bromide is not suitable for treating ALL respiratory disorders such as lung cancer, cystic fibrosis, respiratory infections, etc. Accordingly, the level of predictability of "all" disorders being treatable with the said method, in the art is very low.

(6-7) The amount of direction provided by the inventors and the existence of working examples: Applicants have provided in the specification no disclosure regarding treating any specific respiratory disorder. In fact the specification does not list any disorders. In view of the various different disorders known (and those not yet known) which may or may not be treatable with any of the recited actives, further testing would be necessary to use the invention as broadly as claimed.

(8) The quantity of experimentation needed to make or use the invention bases on the content of the disclosure: The quantity of experimentation needed to make and use the invention based on the contents of the disclosure and the unpredictability asserted by the Applicant, is very high and not enabled by the specification.

Conclusion

For the forgoing reasons, the specification is not enabling for the scope of claim 24.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-23 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, **claim 1** recites the broad recitation, a method of producing hollow microporous particles, and the claim also recites, in particular, which is the narrower statement of the range/limitation.

Claims 1-2 and 4-25 are indefinite for reciting the term “in a given form”. It is not disclosed in the specification what is meant by “given form”. Claim 1 uses the term

multiple times, such as composition is provided in a given form, the volume of given form is increased and fractures are created on the surface of the given form. It is not clear how for example, volume of a form is increased. Furthermore, if form could be any form, it is not clear how one can have fractures on the surface of a solution.

Claim 1 is indefinite for reciting "any other application". The metes and bounds of any other application is not disclosed and the claim is considered indefinite.

Claim 1 is indefinite for reciting the term "up to about". The term "up to" is static while the term "about" is dynamic. Thus employing the two terms together renders the claim indefinite.

Claim 4 recites "as claimed in in claim 1". This appears to be a typographical error, however it is considered indefinite as written.

Claim 8 is indefinite for reciting "in one of claim 7". This appears to be a typographical error, however it is considered indefinite as written.

Claims 8-11 contain the word "Claim" with capitalization. This appears to be a typographical error, however it is considered indefinite as written.

Claim 1 recites the limitation "the structure" in line 11. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite the term structure preceding to this recitation.

Claim 8 recites the limitation "beclomethasone dipropionate" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 7 does not recite beclomethasone dipropionate.

Claim 10 recites the limitation "salbutamol sulphate" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 9 does not recite salbutamol sulphate.

Claim 12 recites the limitation "atomization" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite the term atomization.

Claim 13 recites the limitation "the atomization gas" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite the term atomization gas.

Claim 16 recites the limitation "the evaporation" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 15 does not recite evaporation.

Claim 17 recites the limitation "the lyophilization" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 15 does not recite lyophilization.

Claim 12 is indefinite for reciting "a hair dryer" as a means for atomization.

Regarding claim 14, the word "means" is preceded by the word(s) "of a gas" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claims 9, 12, 14, 15 and 21 as written include the phrase “selected from”. Proper Markush language is “selected from the group consisting of”. There also needs

to be "and" between the last two species of the group. The examiner suggests rewording the claim to include the Markush language. **Note: MPEP 2111.03.**

Claim 20 is vague for reciting "A method A method". This appears to be a typographical error, however it is considered vague as written.

Claim 21 is indefinite for reciting the terms "copolymer and blends thereof", "polymeric medicines" and "genetically engineered polymers". Such terms render the claim indefinite as there is no recognized scope for determining the metes and bounds of the said genus. In other words, there is an indefinite number of species that can fall under the recited genus and specification does not provide any disclosure on which ones work as suitable polymers/excipients.

The remaining claims are rejected for depending on a rejected base claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 and 4-17, 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weers et al (6,638,495) in view of Steiner et al (WO 0059476).

Applicant's claim

Applicant claims a method of producing hollow microporous particles comprising a composition containing one active principle and at least one expansion agent, followed by cooling the composition and wherein all or part of said at least one expansion agent is removed.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Weers et al teach methods, systems and compositions comprising relatively stable dispersions of perforated microstructures in a suspension medium that are preferably administered via aerosolization using pulmonary, nasal, or topical routes (see abstract). The disclosed stable preparations facilitate uniform dose delivery by metered dose inhalers, and allow for more concentrated dispersions. The stabilized preparations provide these and other advantages through the use of hollow and/or porous perforated microstructures that substantially reduce attractive molecular forces, such as van der Waals forces, which dominate prior art dispersion preparations. In particular, the use of perforated (or porous) microstructures or microparticulates that are permeated or filled

by the surrounding fluid medium, or suspension medium, significantly reduces disruptive attractive forces between the particles. Moreover, the components of the dispersions may be selected to minimize differences in polarizabilities (i.e. reduced Hamaker constant differentials) and further stabilize the preparation. Unlike formulations comprising relatively dense, solid particles or nonporous particles (typically micronized), the dispersions of the present invention are substantially homogeneous with only minor differences in density between particles defined by the perforated microparticulates and the suspension medium (see col. 4, lines 4-25).

Weers et al's teachings also provide methods for increasing the effective pulmonary deposition of a bioactive agent using a metered dose inhaler comprising the steps of: associating said bioactive agent with a plurality of perforated microstructures having a mean aerodynamic diameter of less than about 5 .mu.m; dispersing said perforated microstructures in a suspension medium comprising a propellant to provide a respiratory dispersion; and charging a metered dose inhaler with said respiratory dispersion wherein said charged metered dose inhaler provides a fine particle fraction of greater than approximately 20% w/w upon activation (see col. 6, lines 34-48).

Weers et al teach that any therapeutic or diagnostic agent may be incorporated in the disclosed stabilized dispersions. For example, the bioactive agent may be selected from the group consisting of antiallergics, bronchodilators, bronchoconstrictors, pulmonary lung surfactants, antibiotics, leukotriene inhibitors or antagonists, anticholinergics, antiinflammatories, steroids, proteins, peptides and combinations thereof. The perforated microstructures may comprise one or more components (i.e.

structural materials, surfactants, excipients, etc.) in addition to the incorporated bioactive agents. In particularly preferred embodiments, the perforated microstructures will comprise relatively high concentrations of surfactant (greater than about 10% w/w) along with the incorporated bioactive agent(s) (see col. 7, lines 1-19).

Exemplary medicaments or bioactive agents may be selected from, for example, fluticasone propionate, beclomethasone dipropionate, flunisolide, budesonide, ephedrine, formoterol, salbutamol, albuterol, ipatropium, atropine, insulin, glucagon, leuprolide, growth hormones, leukotriene inhibitors etc (See paragraph bridging columns 19 and 20).

Weers et al also disclose surfactants suitable for use in the disclosed dispersions to include saturated and unsaturated lipids, nonionic detergents, nonionic block copolymers, ionic surfactants, and combinations of such agents. Lipids, including phospholipids, from both natural and synthetic sources are particularly compatible with the stabilized preparations. They include phosphatidylcholine, dipalmitoylphosphatidyl-choline (DPPC), phosphatidylglycerol, phosphatidylinositol, glycolipids. Compatible nonionic detergents comprise: sorbitan esters including sorbitan trioleate (Span.RTM. 85), polyoxyethylene (20) sorbitan monolaurate, and polyoxyethylene (20) sorbitan monooleate; copolymers including diblock and triblock copolymers of polyoxyethylene and polyoxypropylene, including poloxamer 188 (Pluronic.RTM. F-68), poloxamer 407. Also synthetic or natural polymers or combinations thereof such as polylactides, polylactide-glycolides, cyclodextrins, polyacrylates, methylcellulose, carboxymethylcellulose, polyvinyl alcohols, polyanhydrides, polylactams, polyvinyl

pyrrolidones, polysaccharides (dextrans, starches, chitin, chitosan, etc.), hyaluronic acid, proteins, (albumin, collagen, gelatin, etc.). Those skilled in the art will appreciate that, by selecting the appropriate polymers, the delivery profile of the respiratory dispersion may be tailored to optimize the effectiveness of the bioactive agent (see col. 16, line 47 to col. 18, line 24).

Weers et al also disclose that while several procedures are generally compatible with the present invention, particularly preferred embodiments typically comprise perforated microstructures formed by spray drying. As is well known, spray drying is a one-step process that converts a liquid feed to a dried particulate form. With respect to pharmaceutical applications, it will be appreciated that, spray drying has been used to provide powdered material for various administrative routes including inhalation.

In general, spray drying consists of bringing together a highly dispersed liquid, and a sufficient volume of hot air to produce evaporation and drying of the liquid droplets. The preparation to be spray dried or feed (or feed stock) can be any solution, course suspension, slurry, colloidal dispersion, or paste that may be atomized using the selected spray drying apparatus. Typically, the feed is sprayed into a current of warm filtered air that evaporates the solvent and conveys the dried product to a collector. The spent air is then exhausted with the solvent. The spray dryers, and specifically their atomizers, may be modified or customized for specialized applications, i.e. the simultaneous spraying of two solutions using a double nozzle technique. More specifically, a water-in-oil emulsion can be atomized from one nozzle and a solution containing an anti-adherent such as mannitol can be co-atomized from a second nozzle.

In many instances the dispersion stability of spray-dried microspheres appears to be more effective if an inflating agent (or blowing agent) is used in their production. Particularly preferred embodiments may comprise an emulsion with the inflating agent as the disperse or continuous phase (the other phase being aqueous in nature). The inflating agent is preferably dispersed with a surfactant solution, using, for instance, a commercially available microfluidizer at a pressure of about 5000 to 15,000 psi. This process forms an emulsion, preferably stabilized by an incorporated surfactant, typically comprising submicron droplets of water immiscible blowing agent dispersed in an aqueous continuous phase. The formation of such dispersions using this and other techniques are common and well known to those in the art. The blowing agent is preferably a fluorinated compound (e.g. perfluorohexane, perfluorooctyl bromide, perfluorodecalin, perfluorobutyl ethane) which vaporizes during the spray-drying process, leaving behind generally hollow, porous aerodynamically light microspheres. Other suitable blowing agents include chloroform, Freons, and hydrocarbons, nitrogen gas and carbon dioxide (see col. 21, line 13 to col. 22, line 13).

Weers et al further disclose multiple examples of preparations of hollow porous particles. It is disclosed that the particles have a volume-weighted mean aerodynamic diameter of about 1.18 μm and a tap density of less than 0.1g/cm^3 (see columns 31 to 38, especially, col. 32, lines 55-62).

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Weers et al do not disclose the specific step of cooling the composition. However the said deficiency is cured by Steiner et al (WO 0059476).

Steiner et al teach improved methods for forming fine particles , the method including steps of dissolving the material in a solvent, immobilizing the dilution solution, and then removing the solvent to yield particles of the material. Immobilization include freezing, gelation and chelation. The preferred method is lyophilization (see abstract).

Steiner et al teach that fine powders are formed by immobilizing dilute solutions of the material forming the powder (i.e. the cargo) and then removing the solvent. Powders are particles having a diameter of less than about 500 μm, preferably from 0.5 μm to 10 μm. The formation of droplets of dilute solution of a cargo in a solvent and the subsequent removal of the solvent leave small residual product particles. If the droplet is frozen prior to removal, then the restricted mobility of the cargo may despite rising local concentration, leave multiple smaller “product” particles per droplet and therefore provides a preferable processing technique (see page 2, lines 20-33).

Steiner et al discloses various methods for the preparation of the powders, one of which includes forming a dilute solution of the material that can be atomized directly into a liquid which is nonsolvent for the material and at a temperature low enough to freeze the dilute solution. Preferably the liquid is selected from nitrogen, argon, oxygen, helium, and carbon dioxide (see page 5, lines 7-11).

Steiner et al discloses other methods (embodiments) which include lyophilization, and dry-gas (see pages 6-7).

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to have modified the teachings of Weers et al by including the step of cooling as taught by Steiner et al because it is disclosed that such methods provide small particles per droplets. Steiner et al teach that employing liquid nitrogen (cold) assists in creating fine particles and it can be added continuously or intermittently during the evaporation process to maintain a relatively constant column profile. In other words, the claims would have been obvious because the technique for improving a particular formulation was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations. Furthermore, unless Applicant demonstrates the criticality of the order of steps and that the prior art is not the same product as the instant application, changes in specific steps has been rendered to be *prima facie* obvious Note MPEP 2144.04 [R-1].

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weers et al (6,638,495) in view of Steiner et al (WO 0059476) as applied to claim 1 and further in view of Trevino et al (7,141,235).

Applicant's claim

Applicant claims a method of producing hollow microporous particles comprising a composition containing one active principle and at least one expansion agent,

followed by cooling the composition and wherein all or part of said at least one expansion agent is removed. Claim 18 recites a mixture of acetone and water in a ratio of 80:20 v/v.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Weers et al and Steiner et al have been discussed above. The combined references lack specific disclosure on the composition comprising acetone and water. This deficiency is cured by Trevino et al.

Trevino et al teach stabilized gas emulsion forming composition comprising a hollow, particulate which upon dissolution in aqueous liquid forms a gas emulsion (see abstract and summary). Trevino et al also discloses the inclusion of an inflating agent in the solution to be spray-dried. Suitable inflating agents include methylene chloride, acetone and carbon disulfide, gases such as nitrogen, carbon dioxide and liquids such as Freon 113, perfluorohexane, perfluorobutane, etc. It is also disclosed that the inflating agent is substantially evaporated during the spray drying process and thus is not present in the final spray-dried powder (col. 9, lines 20-44).

Trevino et al disclose that the each of the first and second surfactant comprises from 0.005 to 20% of the composition (see col. 7, lines 21-25 and col. 8, lines 64-67) and the inflating agent is present at an amount of about 0.5 to 10% of the surfactant solution (see col. 9, lines 46-49).

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the invention was made, given the general teachings of Weers et al and Steiner et al on process of making hollow porous microparticles for inhalation employing a blowing (inflating) agent, to have looked in the art for other specific blowing agents that can be utilized in the same process with the same or better results, such as acetone as taught by Trevino et al with reasonable expectation of success. The claims would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1-2 and 4-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombotz et al (WO 9013285) in view of Weers et al (6,638,495).

Applicant's claim

Applicant claims a method of producing hollow microporous particles comprising a composition containing one active principle and at least one expansion agent,

followed by cooling the composition and wherein all or part of said at least one expansion agent is removed.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Gombotz et al teach process for producing small particles of biologically active molecules. The particles are produced by atomizing solutions of the molecules through a nozzle into very cold liquefied gases, which immediately freeze the atomized droplets (see abstract). The process yields particles of biologically active molecules of greater than 80%. The active agents may be steroids, amino acids, etc (see page 2, lines 20-28 and page 4, lines 15-30). The biologically active molecule is first dissolved in a solvent such as water and buffered to a particular pH level. In order to reduce the particle size of certain molecules to the greatest extent, the molecule should be suspended in a medium in which not only the solvent but also the buffer salts are volatile under conditions of lyophilization. The solution is then atomized and the resulting droplets sprayed into a low temperature liquefied gas using any one of several devices such as ultrasonic nozzles, pressure nozzles, pneumatic nozzles and rotary nozzles. The liquefied gas can be liquefied argon (-185.6°C), liquid nitrogen (-195.8°C), liquid oxygen (-182.9°C) or any other liquid gas that results in the immediate freezing of the atomized particles into frozen particles. The droplets freeze instantly upon entering the cold liquefied gas. The liquefied gas is removed by evaporation at a temperature at which the solvent remains frozen, leaving behind frozen droplets of solvent and biologically active molecules. The frozen solvent is removed from the droplets by lyophilization to

yield porous spheres. The spheres have diameter of from 10 to 90 micrometers (see page 5). The non solvents may be acetone, ethyl acetate, methylene chloride, chloroform and tetrahydrofuran (see page 6, lines 13-18). The porous particles can be used in aerosol sprays for delivery to the lungs (page 6, lines 25-32). The final process step yields particles in the size range of 0.1 to 10 micrometers (see page 7, lines 5-8).

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Gombotz et al lack specific disclosure on beclomethasone dipropionate and the particle tap density. These deficiencies are cured by Weers et al.

Weers et al, discussed above, teach preparation and administration of hollow porous particles comprising active agents such as steroids including beclomethasone dipropionate and the particles size of 0.5 to 10 microns and tap density of less than 0.1 g/cm^3 (see above).

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the invention was made, given the general teachings of Gombotz et al on process of preparing hollow porous particles comprising active agents, to have looked in the art for other specific active agents and particle tap density that can be utilized in the same process with the same or better results, as taught by Weers et al with reasonable

expectation of success. The claims would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

The combined references lack specific disclosure to the ratio of acetone to water. However it would have been obvious to one of ordinary skill in the art to optimize a range or ratio with reasonable expectation of success. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. **In re Aller, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).**

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed 07/27/09 have been fully considered but they are moot in view of the new grounds of rejection.

All claims remain rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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